ISRCTN87639321 https://doi.org/10.1186/ISRCTN87639321

The effects of bisphosphonates on disease activity and bone status in ankylosing spondylitis (BIAS)

Submission date	Recruitment status	[ ] Prospectively registered
04/05/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/05/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/02/2014	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.arc.org.uk/research/grantdet.asp?Code=B0735

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14585

Study information

Scientific Title

Acronym
BIAS

Study objectives
The bisphosphonates will not alter clinical outcome in ankylosing spondylitis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Ankylosing Spondylitis (AS)

Interventions
Placebo or Alendronate 70 mg weekly

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
alendronate

Primary outcome measure
BAS-G

Secondary outcome measures
BASDAI, BASFI and BASRI, ESR, CRP, use of NSAIDs, bone density and vertebral deformity.

Overall study start date
01/08/2004

Completion date
31/08/2006

Eligibility

Key inclusion criteria
Age > 21, stable dose of non-steroidal anti-inflammatory drug (NSAID) for last four weeks. Need to fulfil New York Criteria for AS.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
180

Key exclusion criteria
1. Systemic steroids for the last three months
2. Bisphosphonates in the last 12 months
3. Oesophageal disease or active peptic ulcer
4. Unable to give informed consent
5. Known Paget's Disease
6. Renal disease with creatinine >150 mmol/l, hypercalcaemia, osteomalacia, inflammatory bowel disease, known malignancy and reduced life expectancy <2 years

Date of first enrolment
01/08/2004

Date of final enrolment
31/08/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept of Rheumatology
Bath
United Kingdom
BA1 1RL

Sponsor information

Organisation
Royal National Hospital for Rheumatic Diseases (UK)

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Sponsor type
Not defined

ROR
https://ror.org/05va5gy74

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign 14585

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration